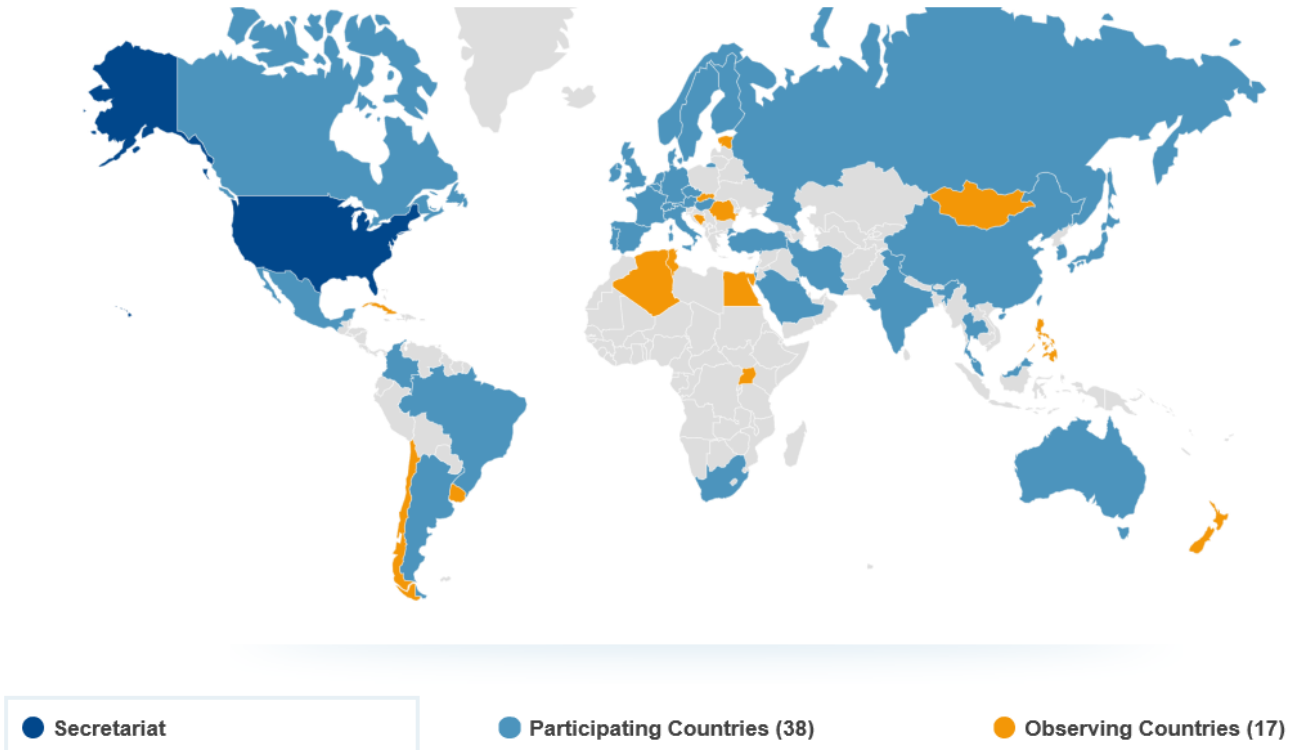
ISO/TC 210 - Quality management and corresponding general aspects for medical devices



Peter Linders, Chair ISO/TC 210

Why do we need ISO standards for health ?

In 2013, nearly **9 %** of the gross domestic product (GDP) of most developed nations (OECD countries) was spent on healthcare*– an enormous part of a country's economy.

More than **1300*** ISO health standards help to ensure these aspirations are achieved.

Good health and well-being are one of the UN Sustainable Development Goals, the United Nations' new roadmap to improve people's lives **by 2030**.

* Source: **www.oecd.org**

Access to :

- health services
- quality care
- safe medical practices and equipment
- cost-effective solutions

has become the expected norm of today's society.

ISO works through its network of national members to bring together the foremost international expertise and disseminate it globally.

ISO standards for health help ensure that individuals and communities receive the quality of care they deserve.

By implementing ISO standards, organizations and companies make a proactive commitment to the principles of quality, transparency, accountability and safety.

ISO standards make it easier to compare health services, exchange information, aggregate data and safeguard the privacy of an individual's health.

Quality management and corresponding general aspects for medical devices

- Secretariat: ANSI
- Secretary: Mr Wil Vargas
- Chairperson: Mr. P.W.J. Linders until end 2018
- ISO Technical Programme Manager: Dr Mary Lou Pelaprat
- ISO Editorial Programme Manager: M. Vincenzo Bazzucchi

Creation date: 1994

ISO/TC 210 – OVERVIEW

- Scope
- Main focus
- Structure
- Work program
- Context & liaisons
- Specific domains
  - Quality management systems
  - Risk management
  - Usability
  - Symbols, Nomenclature
  - Software
  - Essential Principles
  - Small Bore Connectors & Reservoir Delivery Systems
  - Post-market surveillance

ISO/TC 210 – SCOPE

Standardization of requirements and guidance in the field of quality management and corresponding general aspects for medical devices. Standards for small bore connectors.

Excluded:

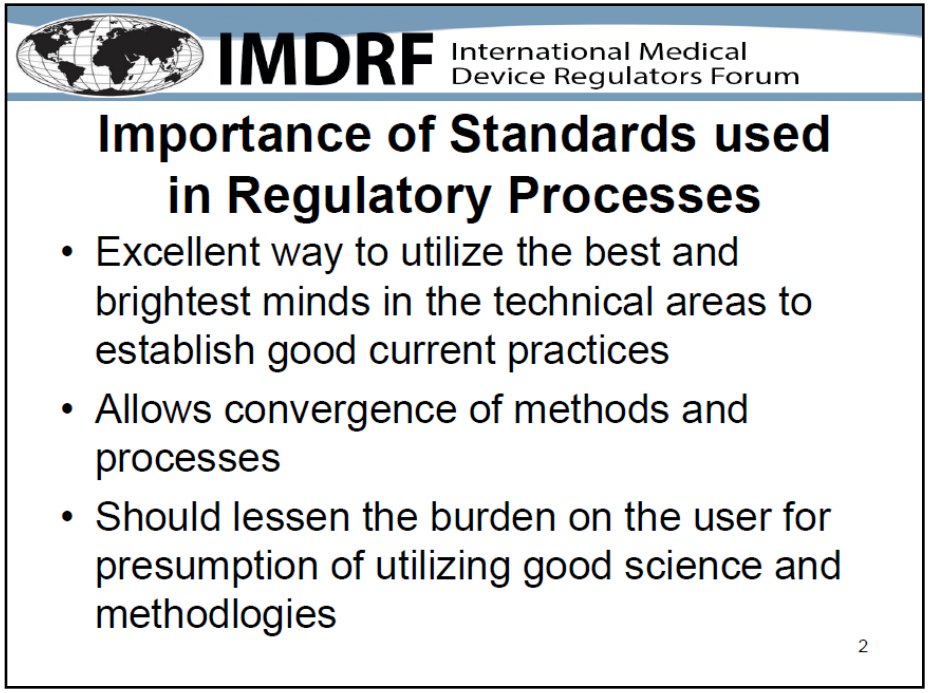
- generic quality management standards dealt with by ISO / TC 176;
- quality management standards for pharmaceutical products;
- technical requirements for specific types of medical devices (Note: Small bore connectors are components of a range of medical devices but are not themselves medical devices).

Note:

In order to promote global harmonization the technical committee may also develop standards on general aspects stemming from the application of quality principles to medical devices, where these are not covered by the scope of another technical committee

ISO/TC 210 – MAIN FOCUS

- Key words
  - For use in regulatory environment
  - Medical devices
  - Quality management
  - Horizontal standards
  - Protect Health & Safety
  - Eliminate trade barriers
  - Global convergence



Kim Trautman (US FDA) in DITTA workshop Kyoto, 2015

ISO/TC 210 – STRUCTURE

ISO/TC 210 Working groups:

- WG 1 **Application of quality systems to medical devices**
- WG 2 **General aspects stemming from the application of quality principles to medical devices**
- WG 3 **Symbols and nomenclature for medical devices**
- WG 5 **Connectors for reservoir delivery systems**
- WG 6/AhWG **Application of post market surveillance systems to medical devices**

Joint Work ISO/TC 210-IEC/SC 62A:

- JWG 1 **Application of risk management to medical devices**
- JWG 2 **Medical device software**
- JWG 3 **Medical device usability**
- JWG 4 **Small bore connectors**

ISO/TC 210 – CONTEXT & LIAISONS

Co-operate, not work in isolation and avoid duplication of work

- IEC and ISO committees (list)

ISO committees in liaison:

ISO/IEC JTC 1/SC 7, ISO/TC 76, ISO/TC 84, ISO/TC 106, ISO/TC 121, ISO/TC 150, ISO/TC 157, ISO/TC 168, ISO/TC 170, ISO/TC 172/SC 5, ISO/TC 172/SC 7, ISO/TC 173, ISO/TC 173/SC 2, ISO/TC 176, ISO/TC 176/SC 2, ISO/TC 194, ISO/TC 198, ISO/TC 209, ISO/TC 212, ISO/TC 215

IEC committees in liaison:

IEC/TC 56, IEC/TC 62, IEC/SC 62A

- Organizations in liaison
  IMDRF (to be invited)

Organizations in liaison (Category A and B):

AHWP, DITTA, EDMA, EUCOMED, EUROM, WFSA, WHO

Organizations in liaison (Category C and D):

GEDSA

ISO/TC 210 – Work programme

ISO/IEC CD Guide 63 Guide to the development and inclusion of safety aspects in International Standards for medical devices
ISO/FDIS 15223-1 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
ISO/DIS 16142-2 Medical devices -- Recognized essential principles of safety and performance of medical devices -- Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
ISO/CD 18250-1 Connectors for reservoir delivery systems for healthcare applications -- Part 1: General requirements and common test methods
ISO/DIS 18250-3 Connectors for reservoir delivery systems for healthcare applications -- Part 3: Enteral applications
ISO/CD 18250-6 Connectors for reservoir delivery systems for healthcare applications -- Part 6: Neural applications
ISO/CD 18250-7 Connectors for reservoir delivery systems for healthcare applications -- Part 7: Connectors for Intravascular Infusion
ISO/DIS 18250-8 Connectors for reservoir delivery systems for healthcare applications -- Part 8: Citrate-based anticoagulant solution for apheresis applications
ISO/DTR 80002-2 Medical device software -- Part 2: Validation of software for medical device quality systems
ISO/DIS 80369-1 Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications

ISO/TC 210 – SPECIFIC DOMAINS

- Specific domains
  - Quality management systems
  - Risk management
  - Usability
  - Symbols, Nomenclature
  - Software
  - Essential Principles
  - Small Bore Connectors & Reservoir Delivery Systems
  - Post-market surveillance

ISO/TC 210 – SPECIFIC DOMAINS
QUALITY MANAGEMENT SYSTEMS

- Key words
  - ISO 13485 published in 2016, revision after 13 years
  - MSS, yet no HLS implemented
  - Sales figures (best seller ISO standard)
  - Link with IAF

Implementation guidance:

- Handbook instead of ISO/TR 14969

55 **About this handbook**

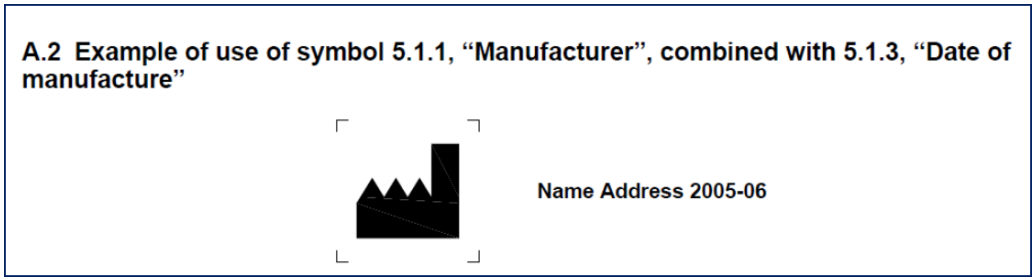
56 **This handbook does not define any requirements, nor add to or otherwise change**
57 **requirements of ISO 13485:2016, and is intended to assist interested parties with**
58 **interpretation and application of ISO 13485.** As all organizations face challenges when develo
59 a quality management system, it is hoped that this guide will be used to provide additional insigh
60 understanding of the requirements in ISO 13485:2016. It is intended for educational purposes a

ISO/TC 210 – SPECIFIC DOMAINS
RISK MANAGEMENT

- ISO/IEC Guide 63:2012
  Guide to the development and inclusion of safety aspects in International Standards for medical devices
- ISO 14971:2007
  Medical devices -- Application of risk management to medical devices

ISO/TC 210 – SPECIFIC DOMAINS
SYMBOLS, NOMENCLATURE

- ISO/FDIS 15223-1
  Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements



- ISO 15225:2016
  Medical devices -- Quality management -- Medical device nomenclature data structure

G•M•D•N

- ISO/TS 19218-1:2011
- ISO/TS 19218-2:2012
  Medical devices -- Hierarchical coding structure for adverse events --
  Part 1: Event-type codes
  Part 2: Evaluation codes

ISO/TC 210 – SPECIFIC DOMAINS
MEDICAL SOFTWARE

- IEC/TR 80002-1:2009 - Medical device software -- Part 1: Guidance on the application of ISO 14971 to medical device software
- ISO/DTR 80002-2 - Medical device software -- Part 2: Validation of software for medical device quality systems
- IEC/TR 80002-3:2014 - Medical device software -- Part 3: Process reference model of medical device software life cycle processes (IEC 62304)
- IEC 62304:2006 - Medical device software -- Software life cycle processes; *Amd1:2015*

ISO/TC 210 – SPECIFIC DOMAINS
SMALL BORE CONNECTORS

Safety of medical device connections in clinical settings

- Historically, one universal type of connector (Luer or the ISO 594 series connector) was used for different applications, e.g. breathing systems, hypodermic, intravascular

- Following a series of accidents, the US FDA (CDRH) endorsed a recommendation to use different connectors for different applications

Luer Lock Luer Slip

Picture Courtesy of Beaumont Hospitals

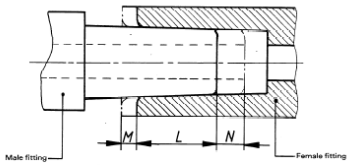


Figure 2 — Typical assembly of 6 % (Luer) conical fittings
(see the corresponding values in the table)

Risks: incorrect delivery, wrong route medication errors

Taken from ISO 594-1

ISO/TC 210 – SPECIFIC DOMAINS
SMALL BORE CONNECTORS

- **ISO 18250 Series:**
  Connectors for reservoir delivery systems for healthcare applications
- **ISO 80369 Series:**
  Small-bore connectors for liquids and gases in healthcare applications
- **Both to replace ISO 594 Series**
  Conical fittings with a 6 % (Luer) taper for “all sorts” of connections

Issues:

- Cost of implementation
- Transition scheme (training, logistics, procurement, …)

ISO/TC 210 – SPECIFIC DOMAINS
POST-MARKET SURVEILLANCE

- Key words
  - Monitor use of products in practice
  - Partially covered in QMS and RM standards
  - Confusing multitude of guidance documents
  - ISO project Still under discussion

Hot News

On 9/9/2016 an New Work Proposal for a Technical Report was launched:

Medical devices -- Post-market surveillance for manufacturers

ISO/TC 210 – FUTURE

- Key words
  - Increasing ‘grey zone’ between medical and health devices
  - “Everything connected to everything else”
  - Dialogue with customers & stakeholders

ISO and health

Great things happen **when the world agrees.**

Thank you